

Safety Evaluation by the DOE Regulatory Unit (RU)
Of Proposed Authorization Basis Amendment Request
ABAR-W375-00-00010,
"Alignment if ISMP and SRD with QAPIP Rev. 5 and
Selection of Quality Assurance Implementing Standard"
(DOE Contract DE-AC06-96RL13308)

1. INTRODUCTION

In accordance with the requirements of RL/REG-97-13, "Regulatory Unit Position on Contractor Initiated Changes to the Authorization Basis," Revision 6, BNFL submitted an Authorization Basis Amendment Request (ABAR) proposing a number of changes to the Safety Requirements Document (SRD) and associated implementing standard portions of the Integrated Safety Management Plan (ISMP).¹ The two essential elements of the ABAR are:

- A proposal to select a tailored version of DOE G-830.120, Rev. 0, "Implementation Guide for use with 10 CFR Part 830.120, Quality Assurance" as an implementing standard for SRD Safety Criteria 7.3-1 through 7.3-11. Doing so replaces the citations to various ISMP sections (and, by reference in the ISMP, various sections of the Initial Safety Assessment - ISA) as implementing standards.
- A number of changes to the implementing standard portions of ISMP and one change to SRD Volume II, Appendix B, "Implementing Standard for Defense in Depth." In addition, the ABAR includes a proposal to use no implementing standard for Safety Criterion 7.3-12. These changes were intended by BNFL to be consistent with the Quality Assurance Program and Implementation Plan (QAPIP), Rev. 5.

BNFL proposed changes to respond to a finding by the RU (IR-99-007-03-FIN) of failure to modify the ISMP and SRD when QAPIP changes affected these documents. Further, the RU made the approval of QAPIP Revision 5 contingent on making the ISMP consistent with the QAPIP.

The effect of the proposed changes to the ISMP and SRD is independent of the use of DOE G-830.120 as a new implementing standard. Therefore, the RU assessed the two elements of the ABAR separately.

2. BACKGROUND

In the SRD, BNFL defines safety criteria (7.3-1 through 7.3-12) related to Quality Assurance (QA). As implementing codes and standards for these criteria, BNFL previously chose to use

¹ Letter, A. J. Dobson to D. C. Gibbs, "Contract No. DE-AC06-96RL13308 - W375 - Alignment of Integrated Safety Management Plan and Safety Requirements Document with Quality Assurance Program Implementing (sic) Plan," dated March 17, 2000.

sections of the ISMP as *ad hoc* subordinate standards, rather than specify nationally or internationally recognized consensus standards. In turn, these ISMP sections refer to sections of the ISA to provide additional detail on how BNFL will implement its QA program. In this ABAR, BNFL proposes replacing the ISMP-based subordinate standards with tailored portions of DOE G-830.120, Rev. 0. Separately, BNFL proposes a number of changes to the ISMP and SRD, the most significant of which is eliminating references to the ISA.

3. EVALUATION

The RU reviewed the BNFL proposal to adopt selected, tailored, portions of DOE G-830.120, Rev. 0 as subordinate standards for Safety Criteria 7.3-1 through 7.3-11. (Separately, BNFL proposes to eliminate the current subordinate standard for Safety Criterion 7.3-12.) The 10 CFR 830.120 requirement regarding standards is:

"The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP."

DOE G-830.120 cites several consensus standards, including ISO 9004 and NQA-1, as providing "acceptable methods for implementing many of the requirements of 10 CFR Part 830.120." It is clear that the authors of DOE G-830.120 did not intend that it would be used as a "consensus standard." It is not a recognized consensus QA standard and no organization maintains the document. (Within DOE, the document was replaced in 1999 by DOE G 414.1-2, "Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1.")

However, the RU recognizes that BNFL may adopt DOE G-830.120 and/or DOE G 414.1-2 as an *ad hoc* standard, provided the *ad hoc* standard is adequately justified. While BNFL states that "(t)his change does not alter the quality assurance program described in the QAPIP," it provides no analysis to demonstrate that the proposed change is consistent with the existing authorization basis. The RU cannot determine from the ABAR why the change is either equivalent to or an improvement over the current use of the ISMP as an *ad hoc* standard. Therefore, the RU does not concur with the proposed change.

In the second element of the ABAR, BNFL proposes a number of changes to the ISMP and one to the SRD. The RU's analysis of these changes is attached (Appendix A). While the RU found several deficiencies in the proposed changes and therefore does not fully concur with this element of the ABAR, most of the changes are acceptable.

4. CONCLUSION

The RU concluded, based on the considerations described above, that BNFL has not fully demonstrated reasonable assurance that the health and safety of the public and the workers will not be endangered by the proposed amendments and the proposed amendments will not have a significant effect on the environment. The proposed amendments do not fully comply with contractual and regulatory requirements and are not fully approved. However, as enumerated in the Appendix to this Safety Evaluation, changes to Safety Criterion (SC) 7.3-1, 7.3-2 (Parts 1 and 2), and 7.3-3 through 7.3-12 are acceptable and are approved. Also, the related changes to

the ISMP described in detail in the Appendix to this Safety Evaluation are approved with the exception of the changes to page 3-7 related to application of the requirements of the Quality Assurance Requirements Document and the changes to page 3-11 and ISMP Section 5.2 related to control of subcontractors. Accordingly, the condition on approval of QAPIP Rev. 4C noted in Reference 2 is satisfied and QAPIP Rev. 5 is approved.